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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/126,559	07/30/1998	DANIEL J. CAPON	11068-043-999	9053

7590 06/27/2005

Jones Day
222 East 41st Street
New York, NY 10017

EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/126,559	CAPON ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *112-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *112-131* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 July 1998* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 112-131 are pending and under consideration in the application. In the prior action, mailed on September 22, 2004, claims 112-131 were pending and rejected. In the Response, filed on May 22, 2005, the Applicant amended claims 112, 115, and 116.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **(Prior Rejection- Withdrawn)** Claims 112-131 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for two reasons. First, it was not clear what was meant by a "sample of host cells." Second, it was not clear if each host cell comprises a plurality of test vectors, or if the Applicant is claiming a method involving a plurality of host cells, comprising different host cells which have been transfected with different resistance test vectors as described by the claims. In view of the arguments presented by the Applicant, and the amendments to the claims, the rejection is withdrawn.

4. **(Prior Rejection- Withdrawn)** Claims 112-114, and 117-121 are rejected under 35 U.S.C. 112, second paragraph because it was not clear what the phrase "corresponding to" referred to in the phrases "a corresponding sample of host cells" transfected with a "corresponding plurality of resistance test vectors." In view of the amendment of the claims, the rejection is withdrawn.

5. **(Prior Rejection- Withdrawn)** Claims 116, and 127-131 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and

distinctly claim the subject matter which applicant regards as the invention. In view of Applicant's arguments in traversal of the rejection on page 8 of the Response, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. **(Prior Rejection- Maintained)** Claims 112-114, 116-121, and 127-131 were rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent Number 6,127,116, issued to Rice et al. The claims have been amended such that they now require that each resistance test vector lacks at least one of the HCV genes necessary for HCV replication. The phrase "HCV genes necessary for HCV replication " is read as including any genes required for either replication of the viral genome or for the production or packaging of the viral capsids. I.e., any of the genes identified in lines 5-9 on page 6 of the application. Applicant traverses the rejection by asserting that the Rice reference does not teach or suggest the use of such replication defective test vectors, or provide any motivation or grounds for a reasonable expectation for their use. Further, the Applicant asserts that the reference actually teaches away from the use of such replication defective vectors. These argument are not, however, found persuasive.

It is first noted that the reference does teach the use of replication defective vectors as an alternative to the fully replication competent viral particles. See e.g., columns 11 (lines 34-41), and 13 lines 10-14. While, as noted by the Applicant, the Rice reference does provide teachings indicating the superiority of fully replication competent viruses, such teachings do not constitute a "teaching away" from the use of the replication defective vectors for the purposes of rebutting a rejection under 35 U.S.C. 103. See e.g., MPEP 2145 XD (quoting the Federal Circuit as stating "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 31 USPQ2d 1130, at 1132 (1994)). That the teachings of the Rice reference may indicate that the replication competent virus may be superior does not teach away from the use of the replication defective vectors as known equivalents therefore, even if they are presented as inferior.

The Applicant further indicates that the reference provides no teachings as to the use of the replication defective particles. However, as indicated above, the reference indicates that such particles are a functional alternative to the use of the replicative particles- insofar as they would be understood to be useful in certain of the disclosed methods in the reference. As was described in prior actions, the reference teaches the use of the HCV particles in methods to determine drug susceptibility. Columns 13-14. The reference teaches that this determination may be made either by the measurement of HCV proteins, or the activity of heterologous reporters encoding by the HCV vectors. Thus, the reference both suggests, and provides a reasonable expectation of success in, the use of the replication defective particles for the determination of the effect of a drug on viral replication or activity.

It is further noted that it was known to those in the art that replication defective particles could be used for the determination of viral or cellular susceptibility to anti-viral drugs. See e.g., U.S. 6,576,622, columns 17-19 (describing examples wherein replication defective viral particles were used to determine such effects- certain of the examples finding support in the parent application 08/585,287 filed on January 11, 1996). Such additional teachings illustrate that those in the art would have had a reasonable expectation of success in the use of the replication defective particles for the determination of antiviral susceptibility as is suggested in Rice. The Applicant's arguments are therefore not found persuasive, and the rejection is maintained.

8. **(Prior Rejection- Maintained)** Claim 115 and 122-126 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rice, further in view of the teachings of Fridland et al. (U.S. 5,576,177) and Bornstein et al. (U.S. Reissue 29,955). The Applicant traverses this rejection on the same grounds as argued with respect to the rejection of claims 112-114, 116-121, and 127-131above. The Applicant asserts that the teachings of Fridland and Bornstein fail to provide the elements missing from Rice. These arguments are not found persuasive for the reasons indicated above. The rejection is therefore maintained.

Double Patenting

9. **(Prior Rejection- Maintained)** Claims 112-131 were rejected in the prior action under the judicially created doctrine of obviousness-type double patenting as being unpatentable over either claims 1, 4, 7-11, 13,14,46-49,51-53,70-73, and 78-83 of U.S. Patent 5,837,464 or over

claims 1,2,18,24-27, and 30-42 of U.S. Patent No. 6,242,187, in view of Lu et al. or Wang et al., and further in view of Rice. The Applicant traverses the rejection on three grounds. First, Applicant argues that the no claim of the '464 patent directs those in the art to the determination of susceptibility of HCV to the indicated drugs, and that no claim of the '187 patent suggests the modification of the claims for determination of HCV susceptibility to antiviral drugs. The Applicant asserts that the Examiner is improperly applying teachings found in the specification as prior art against the claims. The Applicant next argues that the fact that the claims of the patents are dominant to the pending claims is insufficient to demonstrate that the present claims are obvious variations to the patent claims. Finally, the Applicant argues that the teachings of Lu and Wang are no combinable with the teachings of the two cited patents. These arguments are not found persuasive.

The Applicant's first argument in traversal of the rejection, that the Examiner is improperly relying of teachings in the specification that support the claimed invention, rather than looking only to the claims themselves, is not found persuasive. The Applicant's argument is based on the decision of *In re Kaplan* 229 U.S.P.Q. 678 (Fed Cir 1986). The Applicant asserts that the Federal Circuit decision states claims themselves must suggest the variations in the rejected claims. However, as can be seen in the courts decision, the Federal Circuit panel deciding the case spent a significant portion of the background section discussing the relative inventorship of the application, and claims being rejected in the application, as compared to the inventors of the patent claims. 229 U.S.P.Q. at 679-80. This is because the law under which the case was decided required that all the inventors named in the application contributed to all claimed inventions. Thus, because the rejected claims in the application had different

inventorship from the claims in the patent, the claims of the application could not have been claimed in the patent. See, MPEP II.B.2. This law was changed in 1984 so that all named inventors need not contribute to each claimed invention. Thus, the decision of Kaplan is no longer solely determinative of the issue.

Section 804 of the MPEP provides additional guidance as to the use of the specification in double patenting situations. It states that the exclusion of the specification as prior art "does not mean that one is precluded from all use of the patent disclosure." Rather, it notes that the court in the decision of *In re Vogel* (on which the decision in Kaplan was based in part) recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. 164 U.S.P.Q. 619, 622. The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined." Id. Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is based. This is true even where elements are drawn from the specification describing the claimed invention, which are not elements in the claim itself. The Applicant's first argument in traversal is therefore not found persuasive.

The second argument, that domination alone is not indicative of a double patenting problem, is also not found persuasive. While the Examiner notes that the legal assertion is correct, the Examiner is not relying solely on the domination issue. Rather, the Examiner notes

that the claims of the patents are generic to the claims of the present application, and that the additional limitations in the claims are suggested by the teachings of the patents that support the claims therein. Because the Examiner is not relying solely on dominance to demonstrate double patenting, the argument is not found persuasive.

Finally, the Applicant asserts that the teachings of Lu and Wang cannot be properly combined with the patent claims. The Applicants assert that the teachings of these references do not provide suggestion for the modification of the claimed methods of the patents to arrive at the currently claimed methods. In particular, the Applicant asserts that these references provide no basis on which those in the art would modify the claims of the patents to determine the susceptibility of HCV to the antiviral drugs identified in the patent claims. However, as motivation for such a combination may be found in the teachings of the specification providing support for the patent claims in combination with the teachings of Lu and Wand as described in the prior actions (see e.g., pages 3-5 of action mailed on January 28, 2002, and pages 9-11 of action mailed on September 22, 2004), the argument is not found persuasive. The argument appears to be in part reliant on the assertions regarding the use of the specification in double patenting rejections. As these assertions are not found persuasive for the reasons indicated above, the argument is similarly not found persuasive, and the rejection is maintained.

It is noted that the claims have been amended to require that the resistance test vectors must each lack one or more genes necessary for HCV replication. As such embodiments are suggested by Rice as described above, and by the teachings of the Capon patents (see e.g., the '464 patent, column 26 lines 26-46, and the '187 patent columns 37-38) the amendments do not

overcome the rejection. In view of these teachings, and for the reasons above and of record, the rejection is maintained.

10. **(Prior Rejection- Maintained)** Claims 112-115, and 117-126 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8, 9, 12, and 13 of copending application 10/139,069 further in view of Rice. The Applicant traverses the rejection on the basis that the Examiner has improperly relied on teachings in the specification of the copending application to demonstrate that the present claims are obvious variants of the claims in the copending application. This argument is not found persuasive for the reasons indicated with respect to the Capon patents above. The rejection is therefore maintained.

Conclusion

11. No Claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

JAMES HOUSEL 6/24/05
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